Attorney Docket No.: 2001-0572A

Serial No.: 09/831m452

August 22, 2006

## **REMARKS**

Favorable reconsideration is respectfully requested in view of the following remarks.

## I. CLAIM STATUS

Claims 1-3 and 5 were pending in this application when last examined.

Kindly clarify the status of the pending and rejected claims, in particular, claim 1. In items 4 and 6 on page 1 of the Action, it was indicated that claims 1-3 and 5 were pending and rejected. However, claim 1 was not included in any statement of rejection. Accordingly, it would appear that claim 1 is allowed. However, on page 4 of the Action, it is indicated that no claims are allowed. In addition, on page 3 of the Action, it was indicated that the disclosure of the nucleic acid sequence in Yu (AF052135) encompasses the protein of claim 1. Accordingly, it is unclear whether the Office intended to include claim 1 in any rejection. Nonetheless, it is respectfully submitted that claim 1 is novel over Yu (AF052135), because the reference fails to disclose or suggest the hAMSH protein of SEQ ID NO: 1 of claim 1. Therefore, it is respectfully submitted that claim 1 should be indicated as allowed. Kindly clarify the status of the pending and rejected claims.

## II. PRIOR ART REJECTIONS

On page 3 of the Office Action, claims 2-3 remain rejected under 35 U.S.C. § 102(b), as anticipated by Yu et al. (NCBI Accession No. AF052135, August 5, 1998), hereinafter Yu (AF052135).

On page 3 of the Office Action, claim 5 was rejected under 35 U.S.C. § 103(a) as obvious over Yu (AF052135).

These rejections are respectfully traversed.

To anticipate a claim, a cited prior art reference must either expressly or inherently teach each and every element of the claimed invention. <u>See M.P.E.P. § 2131.01.</u>

Attorney Docket No.: 2001-0572A Serial No.: 09/831m452

August 22, 2006

To establish obviousness, three criteria must be met. First, the prior art references must teach or suggest each and every element of the claimed invention. See M.P.E.P. § 2143.03. Second, there must be some suggestion or motivation in the references to either modify or combine the reference teachings to arrive at the claimed invention. See M.P.E.P. § 2143.01. Third, the prior art must provide a reasonable expectation of success. See M.P.E.P. § 2143.02.

Claims 2-3 call for an isolated human gene encoding protein hAMSH of SEQ ID NO: 1 and specific polynucleotide consisting of the 11<sup>th</sup> to 1285<sup>th</sup> nucleotide of SEQ ID NO: 2. Claim 5 is drawn to a recombinant vector comprising such.

As argued in the response of December 7, 2005, Yu (AF052135) fails to disclose or suggest an hAMSH protein, let alone one having the amino acid sequence of SEQ ID NO: 1. In fact, Yu (AF052135) fails to disclose an amino acid sequence. Instead, Yu (AF052135) discloses a nucleic acid, and not a protein. Also, Yu (AF052135) fails to disclose the function of the protein as a signal transduction molecule for cell proliferation.

In reply to these arguments, the Office maintained the rejection on the basis that the nucleic acid sequence in Yu (AF052135) encompasses the hAMSH protein of SEQ ID NO: 1 and the nucleotide sequence of SEQ ID NO: 2.

This position is respectfully traversed.

To start and as noted above, claim 1 is neither anticipated or rendered obvious by Yu (AF052135), because the reference fails to disclose or suggest the hAMSH protein of SEQ ID NO: 1 of claim 1.

In addition, contrary to the Office's position, it is respectfully submitted that a nucleic acid sequence cannot encompass an amino acid sequence, because they are two distinct chemical entities. For this reason alone, Yu (AF052135) cannot encompass the hAMSH protein of SEQ ID NO: 1.

Yu (AF052135) describes a cDNA clone that <u>contains</u> the 1st-1356th nucleotide sequence of SEQ ID NO: 2 of the instant application. That is, the 107th-1462nd nucleotide sequence of Yu (AF052135) is identical to the 1st-1356th nucleotide sequence of SEQ ID NO: 2.

Attorney Docket No.: 2001-0572A Serial No.: 09/831m452 August 22, 2006

However, the rejection is improper, because Yu fails to teach a DNA sequence that encodes a functional peptide. Yu (AF052135) only discloses a 1462 bp nucleic acid sequence (mRNA) and not a peptide. In fact, as discussed above, Yu (AF052135) never discloses any peptide sequence, let alone the hAMSH peptide sequence of SEQ ID NO: 1. Consequently, Yu (AF052135) is not enabling, because the reference never discloses a DNA sequence encoding a complete and functional protein.

In particular, Yu (AF052135) never discloses the <u>coding region</u> for a protein. The coding region starts a the "atg" (Met) codon, but Yu (AF052135) contains <u>three candidates</u> for the start codons (117-119; 127-129; 133-135). Therefore, one of skill in the art cannot ascertain the coding region of hAMSH from the disclosure of Yu (AF052135). In addition, while it may be technologically easy to clone an mRNA using well established procedures, identification of a functional protein from only the mRNA information is not.

Therefore, since Yu (AF052135) does not disclose a DNA sequence encoding a complete and functional protein, the reference cannot anticipate or render obvious the claimed invention.

Furthermore, kindly note that claim 3 is limited to a polynucleotide consisting of the 11th to the 1285th nucleotide of SEQ ID NO: 2. Again, the Office contends that the cDNA clone in Yu (AF052135) "encompasses" this sequence. While it may be correct in that the 1462 bp sequence in Yu (AF052135) is <u>larger</u> than and <u>encompasses</u> the claimed sequence, the reference never identifies the significance of the 11th to the 1285th nucleotide of SEQ ID NO: 2. It is well established that a larger sequence does not anticipate or render obvious a fragment thereof. Thus, Yu (AF052135) fails to disclose or suggest the polynucleotide of claims 2 and 3.

Furthermore, there is no suggestion in the reference to limit the sequence in Yu to the 11th to the 1285th nucleotides of claim 3. Consequently, Yu (AF052135) fails to disclose or suggest the specific polynucleotide consisting of the nucleotide from the 11th to the 1285th nucleotide of SEQ ID NO: 2 (the coding region for hAMSH) of the claims.

Attorney Docket No.: 2001-0572A

Serial No.: 09/831m452

August 22, 2006

Therefore, Yu (AF052135) fails to disclose or suggest each and every element of the claimed invention and Yu (AF052135) lacks a reasonable expectation of success of modifying the teaching in Yu (AF052135) to arrive at the claim invention.

In view of the above, the anticipation rejection of claims 2-3 under 35 U.S.C. § 102(b) over Yu (AF052135) and obviousness rejection of claim 5 under 35 U.S.C. § 103(a) over Yu (AF052135) are untenable and should be withdrawn.

## **CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

Kazuo SUGAMURA et al.

Jon 8 W/11:

Registration No. 48,036 Attorney for Applicants

JFW/akl Washington, D.C. 20006-1021 Telephone (202) 721-8200 Facsimile (202) 721-8250 August 22, 2006